

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date  
14 October 2004 (14.10.2004)

PCT

(10) International Publication Number  
WO 2004/086993 A2

(51) International Patent Classification<sup>7</sup>: A61B 18/14 (74) Agent: MORRIS, James, H.; Wolf, Greenfield & Sacks, P.C., 600 Atlantic Avenue, Boston, MA 02210 (US).

(21) International Application Number:

PCT/US2004/009618

(22) International Filing Date: 29 March 2004 (29.03.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/458,489	28 March 2003 (28.03.2003)	US
60/458,490	28 March 2003 (28.03.2003)	US
60/458,491	28 March 2003 (28.03.2003)	US
60/458,643	28 March 2003 (28.03.2003)	US
60/458,856	28 March 2003 (28.03.2003)	US

(71) Applicant (for all designated States except US): C.R. BARD, INC. [US/US]; 730 Central Avenue, Murray Hill, NJ 07974 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): STEVENS-WRIGHT, Debbie [US/US]; 175 Candlestick Road, North Andover, MA 01845 (US). AMARA, Ryan [US/US]; 57 Beech Street, Tewksbury, MA 01876 (US). BROWN, Erik [US/US]; 10928 SW Collina Avenue, Portland, OR 97219 (US). MACADAM, David [US/US]; 5 Cyndy Lane, Millbury, MA 01527 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

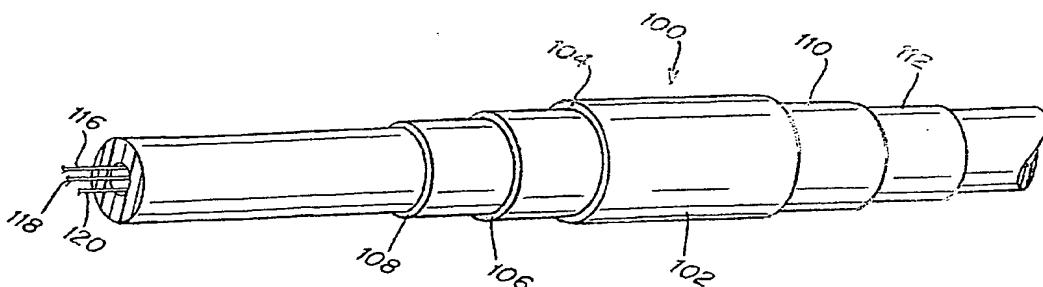
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD; RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD AND APPARATUS FOR ADJUSTING ELECTRODE DIMENSIONS



WO 2004/086993 A2

(57) Abstract: Extendable and expandable ablation electrodes are disclosed. Electrophysiology catheter systems include ablation electrodes that maintain a reduced cross-sectional profile during introduction into a patient and are extendable and/or expandable once positioned at a lesion site. The expanded electrodes having a larger length or and/or diameter can help to produce large lesions. Controllability of the dimensions of the ablation electrodes may be improved.

- 1 -

METHOD AND APPARATUS FOR ADJUSTING ELECTRODE DIMENSIONS

5

## RELATED APPLICATIONS

This application claims priority under 35 U.S.C. § 119(e) to U.S. Provisional Application Serial No. 60/458,489, entitled "Electrode for Electrophysiology Catheter Having an Eccentric Surface", filed on March 28, 2003, U.S. Provisional Application Serial No. 60/458,490, entitled "Electrophysiology Catheter Allowing Adjustment Between Electrode and Tissue Gap", filed on March 28, 2003, U.S. Provisional Application Serial No. 60/458,491, entitled "Shape Shifting Electrode Geometry for Electrophysiology Catheters", filed on March 28, 2003, U.S. Provisional Application Serial No. 60/458,643, entitled "Method and Apparatus for Selecting Temperature/Power Set Points in Electrophysiology Procedures", filed on March 28, 2003, and U.S. Provisional Application Serial No. 60/458,856, entitled "Catheter Tip/Electrode Junction Design for Electrophysiology Catheters" filed on March 28, 2003, all five of which are each incorporated herein by reference in their entireties.

## BACKGROUND OF INVENTION

## 20 1. Field of Invention

The invention relates to medical devices and methods for performing ablation procedures. More particularly, the invention relates to methods and apparatus for extending and/or retracting ablation electrode surfaces *in vivo*.

## 25 2. Discussion of Related Art

The human heart is a very complex organ, which relies on both muscle contraction and electrical impulses to function properly. The electrical impulses travel through the heart walls, first through the atria and then the ventricles, causing the corresponding muscle tissue in the atria and ventricles to contract. Thus, the atria contract first, followed by the ventricles. This order is essential for proper functioning of the heart.

- 3 -

circumscribing the region of the circuit. It should be noted that a complete 'fence' around a circuit or tissue region is not always required in order to block the propagation of the arrhythmia; in many cases simply increasing the propagation path length for a signal may be sufficient. Conventional means for establishing such lesion 5 'fences' include a multiplicity of point-by-point lesions, dragging a single electrode across tissue while delivering energy, or creating an enormous lesion intended to inactivate a substantive volume of myocardial tissue.

The size of a lesion is dependent on many factors, including energy emission and electrode size. Generally, higher applications of electrical power and larger 10 electrodes lead to larger lesion sizes. However, overly high energy delivery can lead to undesirable effects such as tissue desiccation or charring, and in some circumstances, blood coagulation. Increased electrode dimensions present problems with insertion into a patient and introduction into the heart because the larger dimensions can make it difficult to maneuver a catheter through arteries and veins.

15

#### SUMMARY OF INVENTION

Embodiments of the present invention encompass apparatus and method for creating lesions in heart tissue (ablating) to create a region of necrotic tissue which serves to disable the propagation of errant electrical impulses caused by an 20 arrhythmia. Embodiments of the present invention also encompass apparatus and methods for adjusting the dimensions of ablation electrodes that are positioned in a patient.

In one embodiment, a catheter comprises a longitudinal catheter shaft for positioning an ablation electrode within a patient's body. An ablation electrode is disposed on the shaft and has an outer surface. The electrode is convertible from a 25 first configuration in which the electrode outer surface has a first axial size and a first radial size to a second configuration in which the electrode outer surface has a second axial size and maintains the first radial size.

According to another embodiment, a catheter comprises a longitudinal catheter 30 shaft for positioning an ablation electrode within a patient's body. An ablation electrode is disposed on the shaft and has an outer surface. The electrode is

- 5 -

Fig. 3 illustrates a perspective view of the embodiment shown in Fig. 2 with the electrode extended axially.

Fig. 4 illustrates a perspective view of a portion of a catheter shaft and an electrode according to another embodiment of the invention;

5 Fig. 5 illustrates the embodiment shown in Fig. 4 with an electrode surface expanded radially;

Fig. 6 illustrates a perspective view of another embodiment of a portion of a catheter shaft with an electrode surface in a retracted configuration;

10 Fig. 7 illustrates a cross-sectional view of the embodiment shown in Fig. 6 in a retracted configuration;

Fig. 8 illustrates a cross-sectional view of the embodiment shown in Fig. 6 in an expanded configuration;

15 Fig. 9 illustrates a perspective view of a portion of a catheter shaft and an electrode that includes extendable fins according to another embodiment of the invention;

Fig. 10 illustrates a cross-sectional view of the embodiment shown in Fig. 9 with the fins in a retracted configuration;

Fig. 11 illustrates a cross-sectional view of the embodiment shown in Figs. 9 and 10 with the fins in an extended configuration;

20 Fig. 12 illustrates a cross-sectional view of another embodiment of an electrode that includes extendable fins in a retracted configuration; and

Fig. 13 illustrates a cross-sectional view of the embodiment shown in Fig. 12 with the fins in an extended configuration.

25

#### DETAILED DESCRIPTION

This invention is not limited in its application to the details of construction and the arrangement of components and acts set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments and of being practiced or of being carried out in various ways. Also, the phraseology and 30 terminology used herein is for the purpose of description and should not be regarded as limiting. The use of "including," "comprising," or "having," "containing",

- 7 -

application. Furthermore, any of the various features may be incorporated in a catheter and associated methods of use for ablation procedures.

#### Catheter Overview

5 Still referring to Fig. 1, catheter 10 may include a distal tip electrode 18 and/or one or more ring electrodes 20. Distal tip electrode 18 may be affixed to the distal tip of shaft 12 in such a manner as to not move relative to the distal tip, or distal tip electrode 18 may be moveable relative to shaft 12. Catheter 10 may be a steerable device. Fig. 1 illustrates the distal tip portion 18 being deflected by the mechanism  
10 contained within control handle 14. Control handle 14 may include a rotatable thumb wheel (not shown) which can be used by a user to deflect the distal end of the catheter. The thumb wheel (or any other suitable actuating device) is connected to one or more pull wires which extend through shaft portion 12 and are connected to the distal end 18 of the catheter at an off-axis location, whereby tension applied to one or  
15 more of the pull wires causes the distal portion of the catheter to curve in a predetermined direction or directions.

#### Electrodes with Adjustable Dimensions

In producing long lesions, it may be desirable to use a continuous electrode  
20 that extends longitudinally along a catheter shaft. A series of ring electrodes that are spaced axially from one another may not reach all targeted tissue with adequate electrical potential. The potential fields of the series of electrodes do not necessarily sufficiently reach one another and certain volumes of tissue may not receive transmitted energy. Attempts to ablate those tissue volumes by increasing the power  
25 applied to the ring electrodes might result in overlapping potential fields that could lead to tissue overheating.

A single, long electrode may help to create a continuous lesion with a more uniform temperature and/or power distribution. Because electrodes are typically made with stiff materials such as metals, long electrodes can reduce the  
30 maneuverability of the catheter through arteries and veins. It would be desirable to

- 9 -

118 may pass through a pulley (not shown) or around a standoff (not shown) inside shaft 12 so that tension applied in the direction of control handle 14 moves inner electrode portion 108 toward outer electrode portion 104.

Instead of passing pull wires 116, 118 through slot 114, pull wires 116, 118 5 may be attached to slidable magnets on an inner surface of shaft 12. Magnetically coupling these magnets to magnets attached to the electrode portions allows the pull wires 116, 118 to move the electrode portions without the use of a slot or other passage. In other embodiments, a series of electromagnets mounted internally or externally on shaft 12 may be consecutively energized to move electrode portions 10 along shaft 12.

One outer electrode portion 104 and four inner electrode portions 106, 108, 110, 112 are provided in the embodiment illustrated in Figs. 2 and 3, but a greater or lesser number of inner electrode portions may be included. Inner portions 106, 108, 110, 112 do not necessarily have to be positioned entirely within outer electrode 15 portion 104 in a retracted configuration. In some embodiments, extended configurations may provide for electrode portions 104, 106, 108, 110, 112 that do not form a single continuous electrode 102. In these embodiments, the electrode portions may be axially spaced from one another upon extension.

Typically, the further an ablation electrode extends radially from an catheter 20 shaft, the larger the volume of tissue that can be ablated because a larger electrode can extend the potential field further into the domain than a smaller electrode. The diameter of an ablation electrode is limited, however, because the catheter and electrodes move through a patient's arteries and/or veins. An electrode with a large diameter also may be difficult to initially introduce into a patient.

One embodiment of an electrode assembly 200 that extends an ablation 25 electrode surface radially is illustrated in Figs. 4 and 5. In a retracted configuration, shown in Fig. 4, an electrode surface 202 is held closely to an outer shaft portion 204 such that a cross-sectional profile of electrode assembly 200 is not much larger than shaft 12. In an expanded configuration, as illustrated in Fig. 5, electrode surface 202 30 is extended radially away from shaft 12. In the expanded configuration, electrode

- 11 -

200 is slightly larger than the cross-sectional profile of shaft 12. Fig. 6 shows electrode surface 202 in a retracted configuration. Of course, inner shaft portion 204 may extend for a greater length than electrode surface 202.

Fig. 7 shows a cross-section of electrode assembly 200 in a retracted configuration. Inner shaft portion 206 is rotated clockwise to pull a section of electrode surface 202 inside outer shaft portion 204 through a slot 210 in outer shaft portion 204. Because of the reduced length of electrode surface 202 that remains on the exterior of outer shaft portion 204, electrode surface 202 moves inwardly toward outer shaft portion 204 and decreases the overall diameter of electrode assembly 200.

Electrode surface 202 is attached to outer shaft portion 204 by passing first end 208 of electrode surface through a slot 212 in outer shaft 204 and fixing first end 208 to an inside surface 214 of outer shaft portion 204. Similarly, second end 209 may be attached to inner shaft portion 206 by passing second end 209 through a slot 216 in inner shaft portion 206. As should be evident to one of skill in the art, other suitable methods of attaching first end 208 and second end 209 to their respective shaft portions may be employed.

Fig. 8 shows electrode assembly 200 in an expanded configuration. Inner shaft portion 206 is rotated counterclockwise to force a section of electrode surface 202 outside of outer shaft portion 204 through slot 210. With a longer length of electrode surface 202 exterior to the outer shaft portion 204, the diameter of electrode assembly 300 is increased.

In some embodiments, electrode assemblies may be provided that allow adjustment of electrode dimensions in both the radial direction and the axial direction. Such embodiments may include combinations of structures disclosed herein or equivalents.

An electrode surface that extends from shaft 12 along certain radii may allow for deeper embedding of an electrode surface into tissue. Additionally, electric fields may be more directed than with cylindrical electrodes.

One embodiment of an electrode assembly 300 that allows for the extension and retraction of an electrode surface along certain radii is illustrated in Fig. 9. In this embodiment, two fins 302 are extendable from shaft 12. Two fins 302 are shown in

- 13 -

improvements are intended to be part of this disclosure, and are intended to be within the spirit and scope of the invention. Accordingly, the foregoing description and drawings are by way of example only.

What is claimed is:

- 15 -

7. The catheter according to claim 6, wherein the first electrode portion and the second electrode portion are cylindrical.

8. A catheter comprising:  
5 a longitudinal catheter shaft for positioning an ablation electrode within a patient's body; and  
an ablation electrode disposed on the shaft and having an outer surface, wherein the electrode is convertible from a first configuration in which the electrode outer surface has a first axial size and a first radial size to a second configuration in  
10 which the electrode outer surface has a second radial size and maintains the first axial size.

9. The catheter according to claim 8, further comprising an inner shaft portion and an outer shaft portion, the outer shaft portion having a longitudinal slot,  
15 wherein

the ablation electrode comprises a flexible, electrically-conductive plate having a first end and a second end; and

the first end is attached to the outer shaft portion, the plate passes through the longitudinal slot, and the second end is attached to the inner shaft portion.

20 10. The catheter according to claim 9, wherein rotation of the inner shaft portion relative to the outer shaft portion converts the electrode from the first configuration to the second configuration.

25 11. A catheter comprising:  
a longitudinal catheter shaft for positioning an ablation electrode within a patient's body; and  
an ablation electrode disposed on the shaft, the electrode having a continuous outer ablating surface area, wherein the outer ablating surface area is  
30 adjustable; and wherein  
the electrode is substantially comprised of metal.

- 17 -

the second ablation electrode portion is moveable from a first position substantially inside the first ablation electrode portion to a second position substantially outside the first ablation electrode portion.

5        17. The ablation electrode according to claim 16, further comprising a third ablation electrode portion configured for mounting on the catheter shaft, the third ablation electrode portion having a surface configured to emit electrical energy, wherein

10      the third ablation electrode portion is moveable from a first position substantially inside the second ablation electrode portion to a second position substantially outside the second ablation electrode portion.

15      18. The ablation electrode according to claim 16, in combination with a longitudinal catheter shaft for positioning an ablation electrode within a patient's body, wherein the first ablation electrode and the second ablation electrode are mounted on the catheter shaft.

19. The combination according to claim 18, further comprising a pull wire configured to move the second electrode portion.

20

20. A catheter shaft comprising:

an outer shaft portion having a longitudinal passage extending through an outer surface;

an inner shaft portion;

25      an electrode surface with a first end and a second end, the first end coupled to the inner shaft portion, and the second end coupled to the outer shaft portion, wherein

the electrode surface passes through the longitudinal passage;

one of the outer shaft portion and the inner shaft portion is rotatable

30      relative to the other of the outer shaft portion and the inner shaft portion; and

- 19 -

28. the catheter shaft according to claim 27, wherein the ablation electrode member is a fin.

29. The catheter shaft according to claim 27, comprising two ablation 5 electrode members.

30. The catheter shaft according to claim 27, wherein the two ablation electrode members extend in opposite directions to one another.

10 31. The catheter according to claim 24, wherein the ablation electrode member is comprised substantially of metal.

1/6

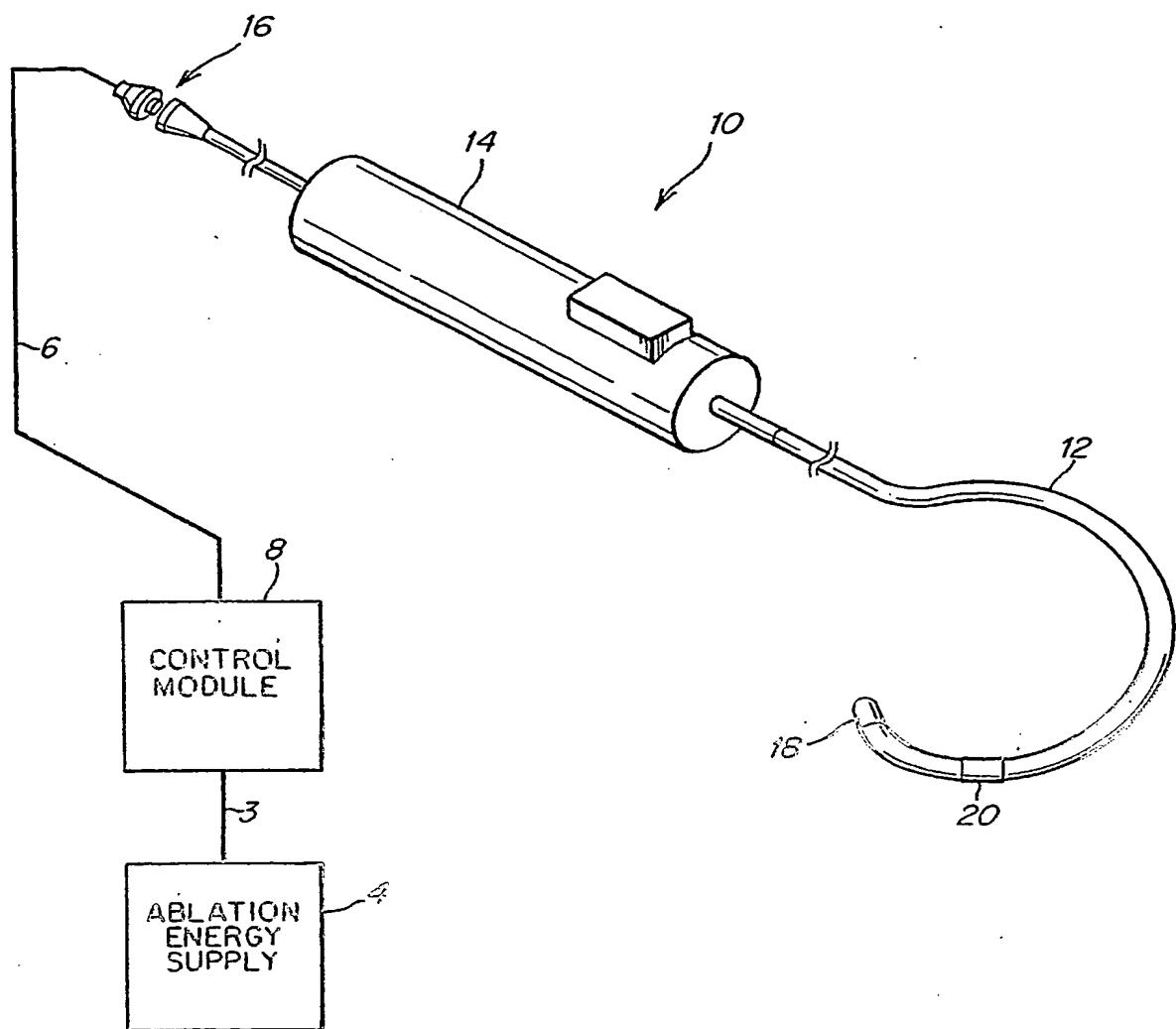


Fig. 1

2/6

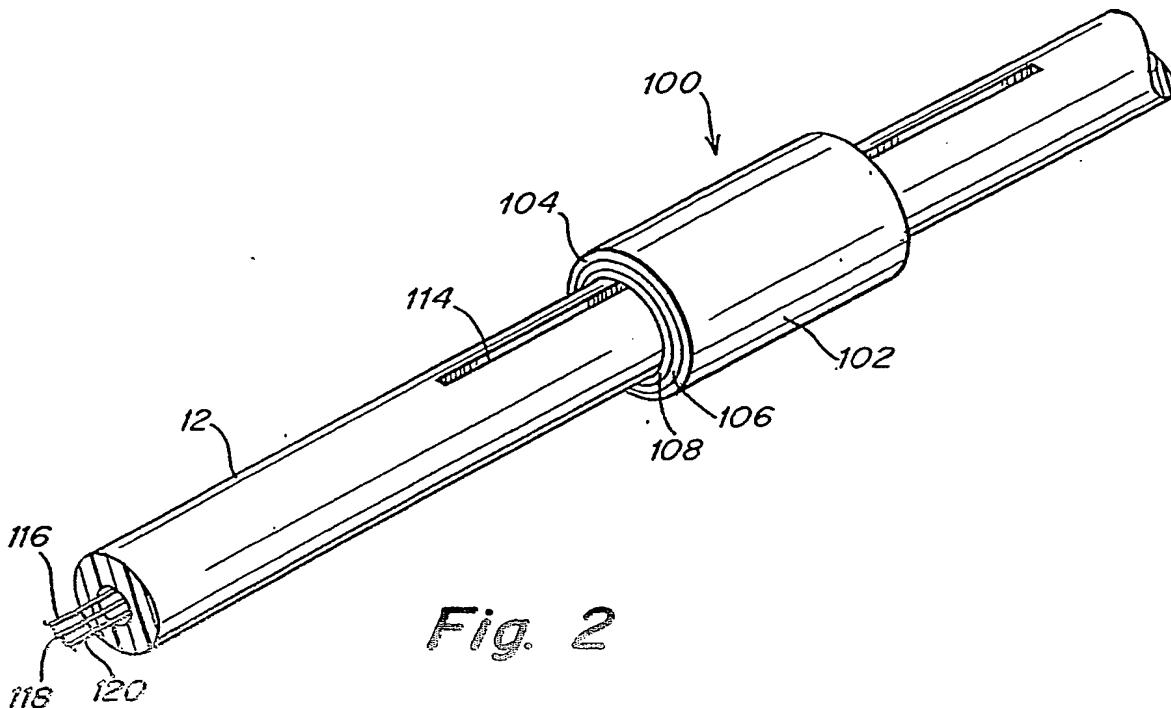


Fig. 2

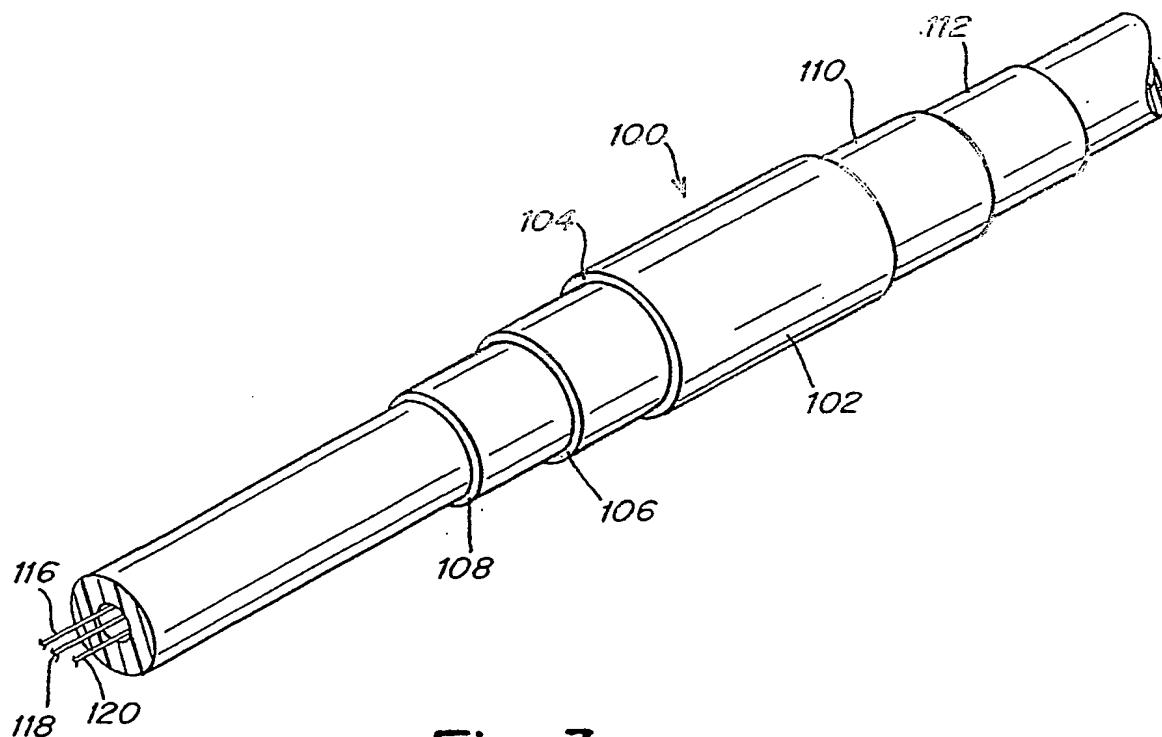


Fig. 3

3/6

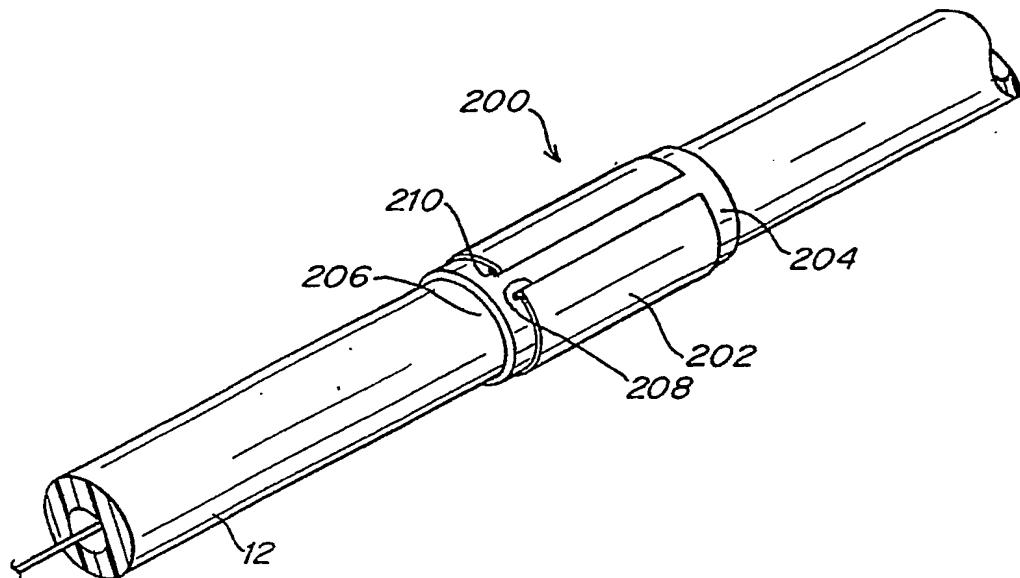


Fig. 4

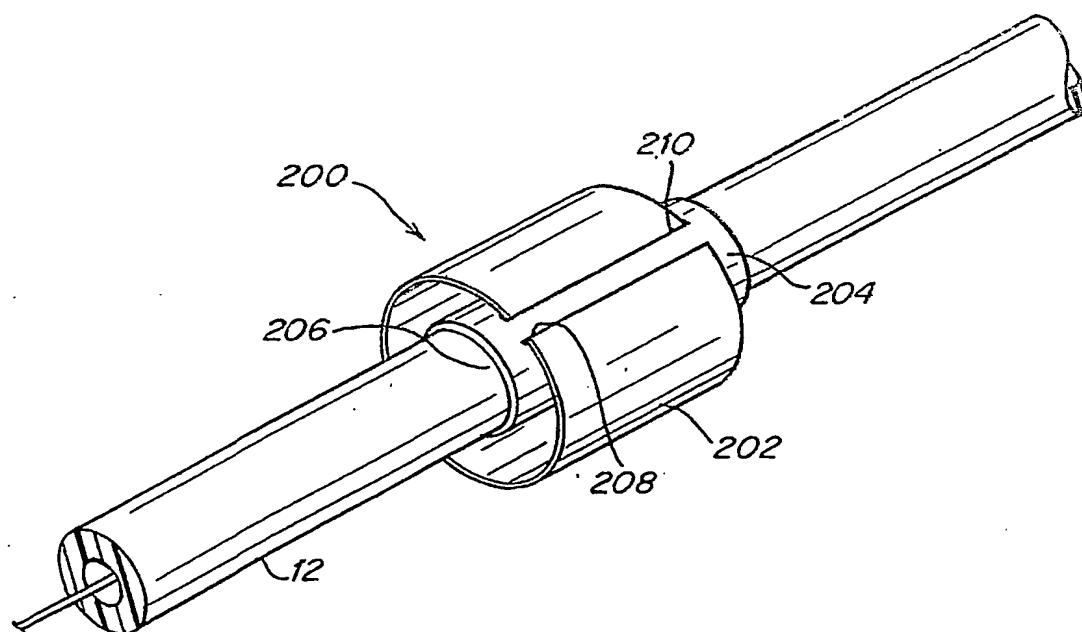


Fig. 5

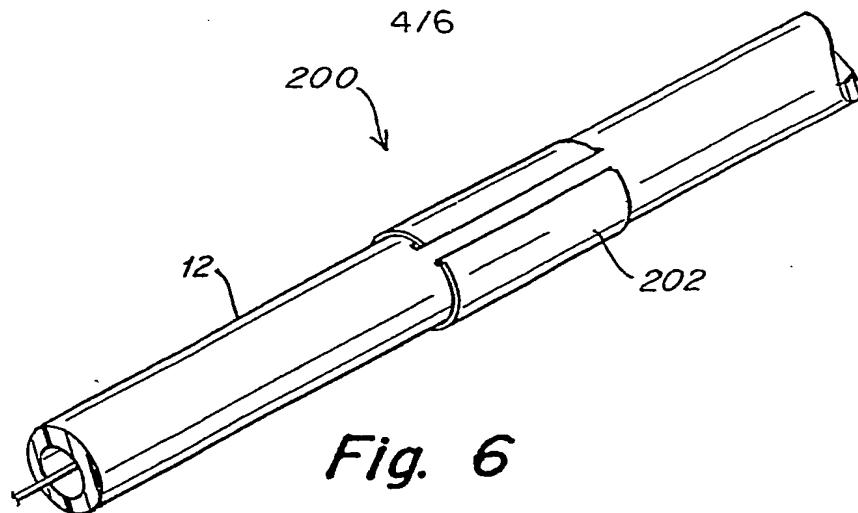


Fig. 6

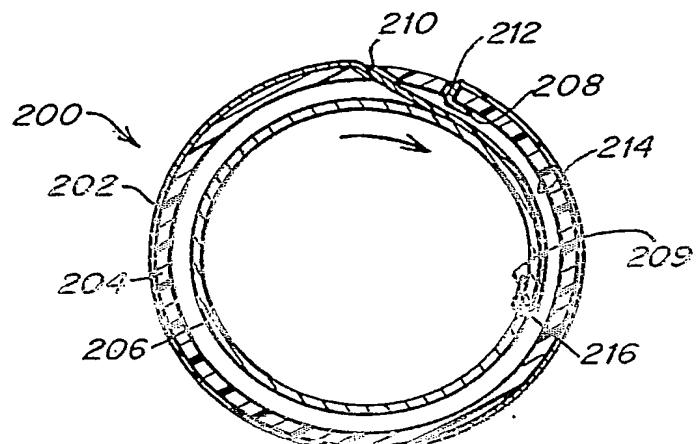


Fig. 7

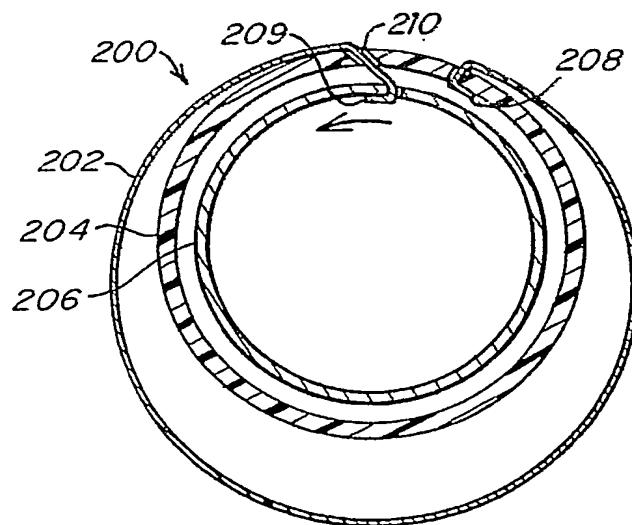


Fig. 8

5/6

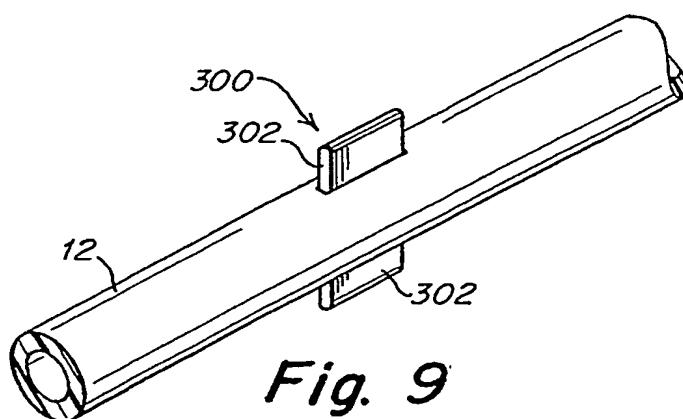


Fig. 9

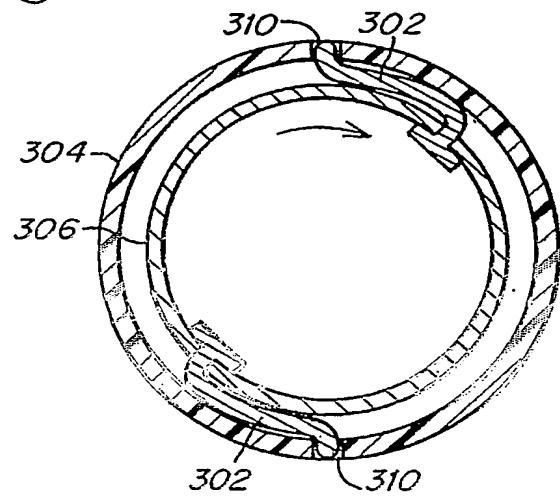


Fig. 10

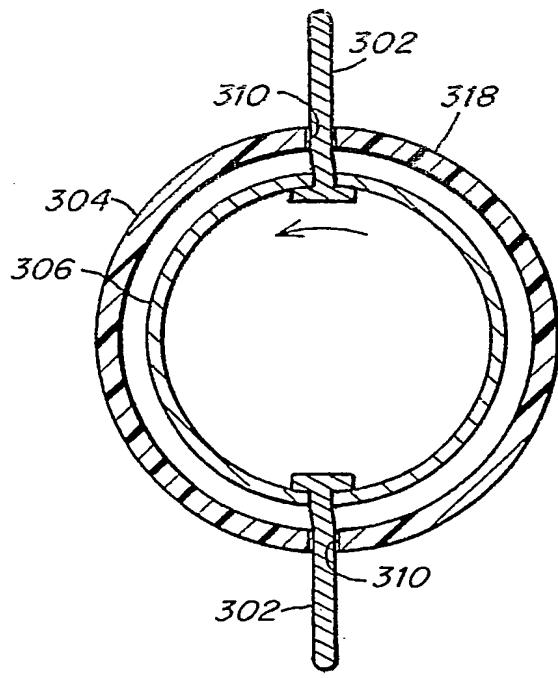


Fig. 11

6/6

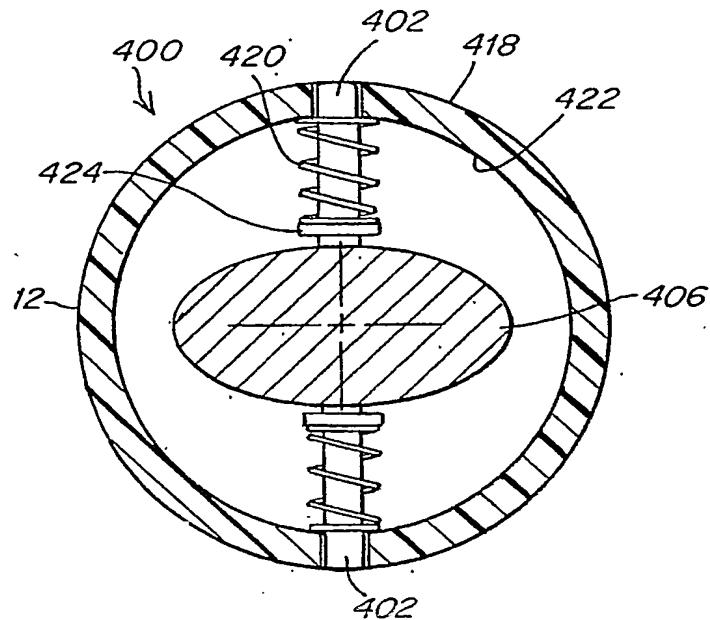


Fig. 12

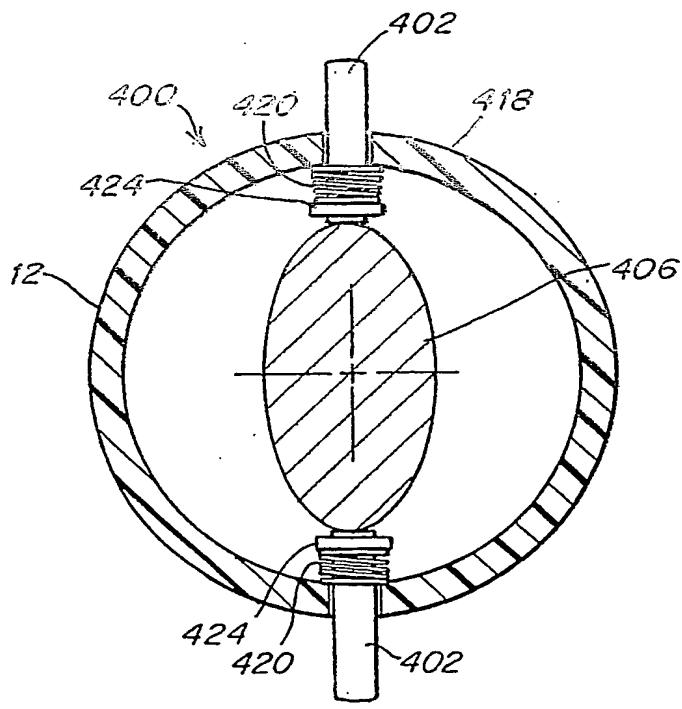


Fig. 13